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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/471, 789 12/23/99 HILLMAN

J PF-0519-1DIV

EXAMINER

LEGAL DEPARTMENT
INCYTE GENOMICS INC
3160 PORTER DRIVE
PALO ALTO CA 94304

HM22/0619

HARRIS, A

| ART UNIT | PAPER NUMBER |
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1642

DATE MAILED:

06/19/01

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

| | | |
|--|--|---------------------------------------|
| | Application No. 09/471,749 | Applicant(s) Hillman et al. |
| | Examiner Alana M. Harris, Ph. D. | Art Unit 1642 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on March 22, 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 3, 6, 7, 9-12, 19-25, 27-30, and 41-45 is/are pending in the application.

4a) Of the above, claim(s) 3, 6, 7, 9-12, 19, 20, 23-25, 29, 30, 41, and 42 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 21, 22, 27, 28, and 43-45 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2

20) Other: _____

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DETAILED ACTION

Response to Amendment

1. Claims 3, 6, 7, 9-12, 19-25, 27-30 and 41-45 are pending.

Claims 43-45 have been added.

Claims 21 and 22 have been amended.

Claims 26 and 31-40 have been canceled.

Claims 3, 6, 7, 9-12, 19-20, 23-25, 29, 30, 41 and 42, drawn to non-elected inventions are withdrawn from examination.

Claims 21, 22, 27, 28 and 43-45 are examined on the merits.

Information Disclosure Statement

2. Applicants' response to the Examiner's communication mailed December 18, 2000 (Paper No. 9) has been noted and considered. Applicants are advised to review Appendix R - PATENT RULES, Title 37 - Code of Federal Regulations Patents, Trademarks, and Copyrights. 37 CFR § 1.3 reads that "Business [is] to be conducted with decorum and courtesy. Applicants and their attorneys or agents are required to conduct their business with the Patent and Trademark Office with decorum and courtesy. Papers presented in violation of this requirement will be submitted to the Commissioner and will be returned by the Commissioners direct order. Complaints against examiners and other employees must be made in correspondence separate from other papers."

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As indicated on the accompanying PTO-1449 the Examiner has accessed and reviewed some of the documents that were listed on the IDS (Paper No. 2). Further, Applicants have not supplied the year of Documents 9-20 listed on the IDS in which they want considered, hence these documents were not considered. Applicant is *invited* to provide replacement copies of listed references for consideration.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

Claim Rejections - 35 U.S.C. § 112

4. The rejection of claims 21, 22, 27 and 28 under 35 U.S.C. 112, first paragraph in relation to a specific and substantial asserted utility or a well established utility is withdrawn.

Claim Rejections - 35 U.S.C. § 101

5. The rejection of claims 21, 22, 27 and 28 under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility is withdrawn in view of Applicants' arguments.

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Claim Rejections - 35 U.S.C. § 102

6. The rejection of claims 21 and 27 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent #5,919,660 (filed June 24, 1997) is withdrawn in view of Applicants' amendment to claim 21.

7. The rejection of claim 21 under 35 U.S.C. 102(b) as being anticipated Accession #A55302 (July 8, 1995) or Gabig et al. (J. Biol. Chem. 269:29515-29519, 1994) is withdrawn in view of Applicants' amendment to the claim.

Claim Rejections - 35 U.S.C. § 103

8. The rejection of claims 21 and 27 under 35 U.S.C. 103(a) as being unpatentable over Accession # A55302 (July 8, 1995) or Gabig et al. (J. Biol. Chem. 269:29515-29519, 1994), in view of Harlow and Lane (Antibodies, A Laboratory Manual, Cold Spring Harbor Laboratory, 1988) is withdrawn in view of Applicants' amendment to claim 21.

New Grounds of Rejection

Claim Rejections - 35 U.S.C. § 112

9. Claims 21, 27, 28 and 43-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement commensurate with the scope of the claimed invention. The specification does not enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claim 21 is broadly drawn to a biologically-active fragment, as well as a immunogenic fragment of SEQ. ID. NO:3 or SEQ. ID. NO:5 comprising at least 30 contiguous amino acid residues. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the number of proteins broadly encompassed by the claims and the claims broadly encompass a significant number of inoperative species. Since the amino acid sequence of a protein determines its structural and functional properties, knowledge of which sequences of the amino acids would retain similar biological activity and immunogenicity the same as Applicants' is required. The disclosure does not provide any information disclosing what fragments of SEQ ID NO:3 or SEQ ID NO:5 should be regarded as biologically active or immunogenic. The specification exemplifies no examples of the effective use of the sequences consisting of SEQ ID NO:3 or SEQ ID NO:5, nor fragments of these polypeptides as a pharmacological agent and no such uses are art known. Therefore, due to the unpredictability of therapeutics and the absence of any evidence concerning the effectiveness of the claimed pharmaceutical composition as a pharmacological agent, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected,

Applicants have not provided sufficient guidance to enable one of ordinary skill in the art for the intended use of the claimed proteins as a therapeutic agent. The scope of the claims must bear a reasonable correlation with the scope of enablement. In view of the lack of guidance, lack of examples, and lack of predictability associated with regard to using the myriad of contiguous

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amino acid residues encompassed in the scope of the claims, one skilled in the art would be forced into undue experimentation in order to practice the broadly claimed invention.

Maintained Rejections

Claim Rejections - 35 U.S.C. § 112

10. The rejection of claims 21, 22, 27, 28 and newly added claims 43-45 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

Applicants argue that “while identifying a polynucleotide sequence, and the polypeptide encoded by the polynucleotide sequence, was a major undertaking at one time...sequencing and sequence assembly have greatly simplified the process.” While the Examiner concurs with this Applicants’ have yet to identify what amino acid substitutions, deletions and insertions would be allowed that would yield variant with at least 90% amino acid sequence identity to SEQ Id NO:3 and SEQ ID NO:5. For these reasons, as well as for the rejection are of record in paper no.8, mailed June 20, 2000 the rejection is maintained.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris whose telephone number is (703)306-5880. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate

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Fridays off. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703)308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703)308-0196.

Alana M. Harris, Ph.D.
Patent Examiner, Group 1642
June 18, 2001

Sheela J. Huff
SHEELA HUFF
PRIMARY EXAMINER